Charles University in Prague
Faculty of Social Sciences
Institute of Economic Studies

Bachelor Thesis

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The Czech Pharmaceutical Industry:

Do specific features of the relevant market provide sufficient incentives for an effective informal regulation?

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Prohlášení

Prohlašuji, že jsem bakalářskou práci vypracoval samostatně a použil pouze uvedené prameny a literaturu.

Souhlasím s tím, aby práce byla zpřístupněna veřejnosti pro účely výzkumu a studia.

V Praze dne 21.5.2010 .....…..……..

Miroslav Stacho

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Last but not least, I would like to thank my parents for their intensive support and patience.

Abstract

The bachelor thesis ‚*The Czech Pharmaceutical Industry: Do specific features of the relevant market provide sufficient incentives for an effective informal regulation?*' provides an overview of specific features of relevant market. Based on both empirical and theoretical findings it attempts to justify sufficiency of drug producers' incentives for an effective self-regulation of their (un)ethical conduct. The overview in the first part of the thesis includes brief description of R&D process, statutory interventions before and after a new drug is introduced to the market, area and tools of self-regulation enfocement. Subsequently, a model combining conclusions from previous chapters, additional relevant studies and practical experience from Czech market is drafted and tries to answer central question of the thesis whether sufficient incentives exist for the producers to monitor themselves effectively.

Keywords: *Czech pharmaceutical industry, self-regulation, statutory regulation, ethical code, incentives*

Abstrakt

Bakalárska práca ‚*Český Farmaceutický Priemysel: Poskytujú špecifické črty relevantného trhu dostatočné stimuly pre efektívnu neformálnu reguláciu?*' popisuje špecifické rysy analyzovaného trhu a na základe empirických ako aj teoretických zistení sa pokúša obhájiť motiváciu výrobcov liekov efektívne využívať samoregulačné praktiky v oblasti ich (ne)etického konania. Prehľad v prvej časti práce zahŕňa stručný popis procesu výskumu a vývoja nového lieku, sprievodných a následných regulačných zásahov štátu a oblasť právomocí samoregulácie a prostriedkov jej vymáhania. Nasleduje formulácia modelu založeného na záveroch predchádzajúcich kapitol, zistení iných autorov a praktických skúsenosti z Českého prostredia. Model sa pokúša odpovedať na ústrednú otázku existencie dostatočných stimulov pre efektívnu samoreguláciu výrobcov liekov pôsobiacich na Českom trhu.

Kľúčové slová: *Český farmaceutický priemysel, samoregulácia, štátna regulácia, etický kódex, stimuly*

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1 Introduction

"It is hard to think of many industries that have contributed as much to human welfare as the pharmaceutical industry."
Levy, Wickelgren (2001)

The authors of prelimenary statement, Levy and Wickelgren, are surprisingly not executives of pharmaceutical company, but representatives of regulatory institution[1] and apart from direct empirical evidence such as average age prolonging, the unique importance of pharmaceutical industry has been prooved by many detailed studies.[2] On the other hand, there are many different reasons for unethical behaviour in pharmaceutical industry. The great pressure on business success of developed drugs determined by the expense and riskiness of the whole process, the competition composed of original and generic drugs' producers that can be untransparent, the often indistinguishable difference between educating doctors and corruption plus several others coerced the companies to cooperatively establish and enforce ethical rules all over the world. Along with government interventions, an institutional alternative of industry self-control has developed. Self-regulation as an alternative to statutory regulation with both advantages and disadvantages has its characteristic features that need to be taken into consideration while analysing its actual implementation. Pharmaceutical industry also belongs to the industries with specific peculiarities arising from R&D costs, dealing with human health and complicated legislation. Although those seem to provide ideal predispositions to prefer enforcing rules through self-regulatory institutions, a lot of different aspects need to be carefully taken into consideration while assessing incentives of particular market players - especially producers with significant market shares - to take such self-enforced rules seriously.

[1] Federal Trade Commission

[2] E.g. Lichtenberg (2001)

1.1 Outlining the topic and setting it in context

The costs of promoting newly introduced drugs have been growing rapidly and after the R&D costs they are the second most significant expenditure for a pharmaceutical company.[3] However, there need to be distiguished between socially beneficial promoting and unethical promoting considered as corruption. The basic idea of this study is to combine empirical experience of Czech self-regulation organizations' (SRO) representatives with specific features of the investigated industry and theory based on existing literature. One of the conditions of meaningful self-regulatory system is measurability.[4] As the thesis proceeds it is more and more obvious that impact of self-regulation in the Czech pharmaceutical industry could be indirectly measured, there have just not been proper methods defined yet. Another key aspect is belief of the author of the study there is a great potential for even more extensive self-regulation as a complement to statutory regulation in the industry. However such an extension can be confidently suggested only after more detailed analysis than that undergone in next chapters. The reason is the role of correct interpretation of relevant signals determining the success of changes in regulation seems to be even more crucial for further activities of SROs and their bargaining power when dealing with the government. Last but not least, the whole decision making process of a producer based on his incentives in current conditions need to be taken into consideration and carefully discussed. This thesis deals with relationship between theoretical and empirical conclusions based on detailed descriptions rather than analyzing particular ethical issues that should be covered. They should be effectively set by firms themselves if they sincerely prefer own regulation of their activities. Parallelly, economic reasons of sector's uniqueness and its consequences are being introduced.

[3] Drake, Uhlmann (1993)

[4] Blumrosen (1983): '*The results to be achieved must be measurable'*

2 Topic overview and initial literature review

2.1 Self-regulation vs Governmental regulation

The basic idea of self-regulation stems from the relationship between regulation and competition that should be considered complements in a specific settings of market-driven economy. It is the '*deliberate delegation of the state's law-making powers to an agency, the membership of which wholly or mainly comprises representatives of the firms or individuals whose activities are being regulated*' (Ogus 1999, p. 590).[5] Although self-regulation as an alternative to direct government regulation has recently received a lot of theoretical and empirical attention from economists, existing studies focus on the analysis of social welfare, and are rather general, not concentrating on specific industry, which is confirmed in several assessing papers, e.g. '*They are in the aggregate quite inconclusive'* (Grajzl, Murrell 2005, p.1). To be concrete, the older the study is, the more critical to ideas of deregulation of statutory control it seems to be. Leland (1979), Shaked and Sutton (1981) describe the undesirable anti-competitive effects of self-regulation. In contrast, Kranton (2003), Lyon and Maxwell (2000) argue that self-regulation may improve social welfare. On the contrary, Gehrig and Jost (1995) had been, according to the Grajzl and Murrell paper, '*the only account in the literature that evaluates the social welfare properties of self-regulation by explicitly contrasting it with direct government regulation*.' Furthermore, slightly critical but rather precise analyses of SROs decision-making possibilities have been performed by Nunez in 2001 and 2007. Throughout the thesis, several other relevant papers and their findings are introduced where it is useful. Finally, Grajzl and Murrell argue that self-regulation is efficient when '*there is much uncertainty about the results of institutional implementation, when the government is populist, or when society is not polarized*.' Many of the features of populistic government as defined in their paper as well as variation in regulatory arrangements across the countries can be seen in most of the countries of European Union, however, the justification of firms' incentives tries to be as certain as possible in this thesis. All in all,

[5] As quoted in a paper by Peter Grajzl and Peter Murrell: Allocating Law-Making Powers: Self-Regulation vs. Government Regulation (2005)

it is neccessary to mention that most of the literature formalizes self-regulation activities in general, however, the concern of the thesis is a very specific environment of pharmaceutical industry and its members' ethical conduct.

Even with general approach, there are a lot of reasons self-regulation should be preferred to statutory regulation and implementing additional legal rules is more expensive under government regulation than under self-regulation. Firstly, producers possess greater knowledge of preferences and available resources.[6] Secondly, self-regulation is less formalised and less rigid. That is why we sometimes refer to **informal** regulation. It is more likely not to obstruct innovation or limit individual consumer choice.[7] Thirdly, monitoring and enforcement costs of self-regulatory arrangements are significantly lower as well. Moreover, the costs are borne by firms themselves and they have more incentives to minimize costs of enforcement than the government has with taxpayer money.[8]

On the other hand, there are also several threats when delegating responsibility of regulation to firms themselves. The main is a regulatory capture saying the firms may be missing sufficient incentives to control their own quality and standards that will be introduced in more detail later in the text. The association of firms can also start to behave as collusion with its negative economic consequences.

For self-regulation activities to be effective, they have to be enhanced by sufficient competition. In the industry producing credence goods that are often irreplaceable for people with temporary or permanent health troubles and therefore without or with only a few substitutes it seems even more important to sufficiently evaluate industry interests.

[6] F.A.Hayek in The Use of Knowledge in Society (1945) states the assumptions on construction of a rational economic order: 'If we possess all the relevant information, if we can start out from a given system of preferences, and if we command complete knowledge of available means, the problem which remains is purely one of logic …'

[7] Miller (1985)

[8] We may refer to *moral hazard* here

2.2 Regulation of pharmaceutical industry within European Union

A competitive European pharmaceutical industry within activities of the European Commission is a part of the Lisbon strategy agenda. In healthcare, generally, the European Union shares competences with its Member States. Although the rules of regulation are not harmonised on a European level, those states are responsible for providing heath services and medical care within their territories (article 152 of the Treaty establishing the European Community).

3 Specification of Hypotheses and Ideas of Its Testing

The aim of the thesis is to confirm the hypothesis that firms and self-regulatory organizations (SROs) those firms subsequently form have enough incentives to enforce their codes in a way that is more effective than potential statutory regulation performed by government[9] not only in theory but also in practice and its development is going in the right direction.

Firstly, pharmaceutical industry is a sensitive and to a great extent unexplored, rapidly developing area. Therefore, relevant theoretical and empirical backgrounds need to be introduced and taken into consideration regarding particular steps of R&D and regulatory hurdles leading to a drug‘s introduction to the market.

Secondly, the assumptions of such a self-regulatory regime have to be analyzed and confirmed. As mentioned before, general assuptions have been formulated in several papers dealing with self-regulation itself. Using empirics, available sources, knowledge and information obtained thanks to representatives of SROs, this thesis tries to confirm or reject those preconditions and suppostitions as well as to distinguish between relevant and irrelevant ones regarding specific features of the industry and the market pertaining to it.

Thirdly, the thesis tries to set up a suitable model and ideas for its extension, based on existing literature and own findings and observations, combining different approaches to

[9] Within covered ares, discussed in chapter 5

achieve the most satisfactory tool for formalizing the relationships and effects in the industry based on activities that are subject to self-regulation. Using the conclusions from all the chapters this thesis would hopefuly be able to evaluate whether firms have enough incentives to adopt self-regulation that is convenient for the patients and whether the current trends on the relevant market of Czech pharmaceuticals are going in the right direction.

4 Process of drug's Research & Development

Pharmaceutical industry is a highly regulated industry whether considering original drugs or subsequently produced generic drugs. This chapter briefly describes the whole process of drug development and regulatory practices it collides with on its way from discovery to becoming publicly available helping to depict general framework needed for further analysis.

4.1 Phases of R&D

According to EFPIA[10] sources and calculations, the estimation in 2007 showed '*the average cost of researching and developing a new chemical or biological entity is €1,059 million and it takes an average of 10-13 years'* to bring it in a form of a new medicine to the pharmacy. On the graph (Figure 1) we can see rapid growth of the costs over last few decades. These costs are mostly covered by private investments nowadays. Considering this rapidly increasing trend, increasing effort over time to attract private investors has been also required. The effort cannot be intensified unless consistent rules and positive conditions are achieved. The thesis deals with the draft definitions of these in the following chapters.

[10] European Federation of Pharmaceutical Industries and Associations, introduced in chapter 5

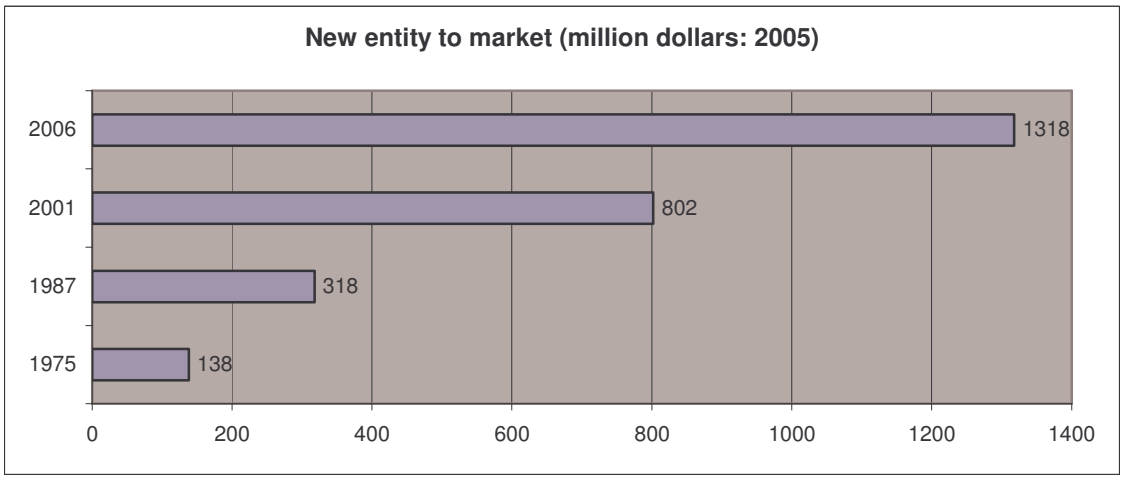


Figure 1: Estimated total costs of bringing a new entity to pharmacy, in million "dollars of the year 2005". Source: DiMasi J.A., Grabowski H.G. (2007), modified

Mansfield (1986) presented research performed in the US saying that without patent protection the pharmaceutical companies would restrict their research and development by 60%. Also Carnegie Mellon Survey (1994) confirmed there is an additional positive benefit of patents to pharmaceutical companies that is not present in other industries. Optimal length of patent duration is characterized as the intersection of marginal social expenditure on patent and marginal social benefit from it. The length of the particular segments of the entire process of a new successfully developed drug's R&D is depicted in Figure 2.

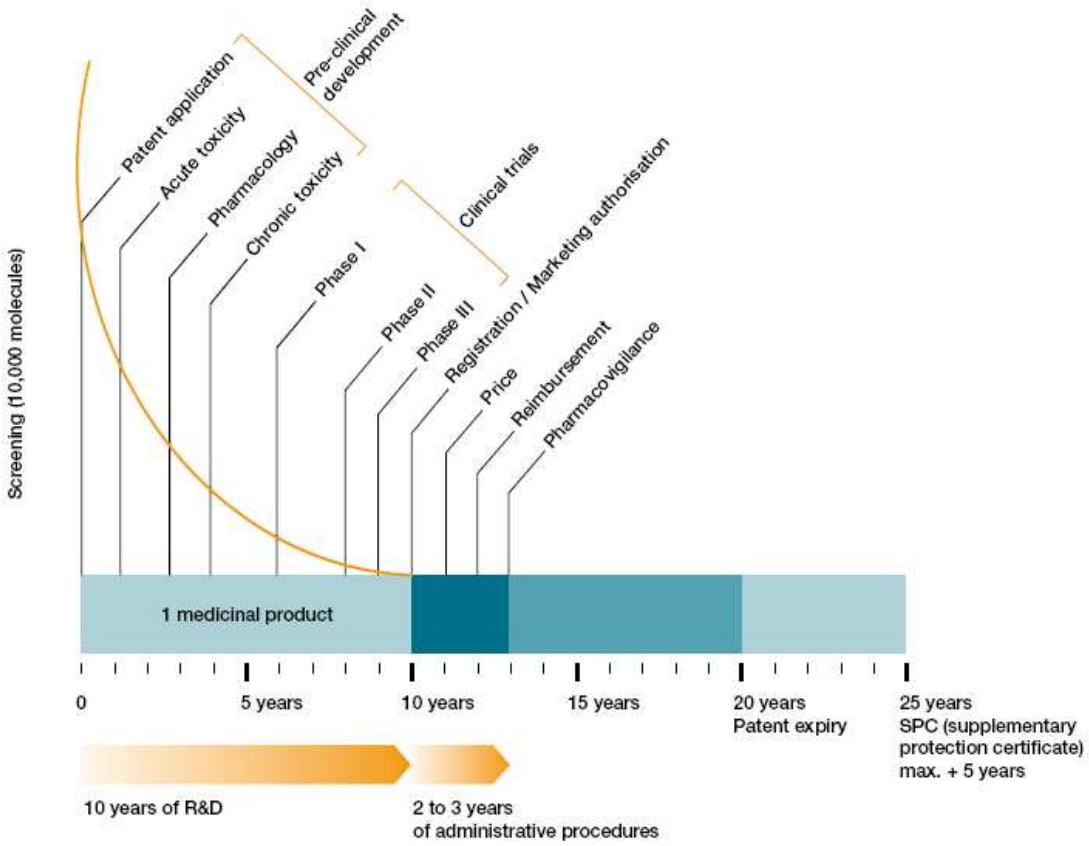


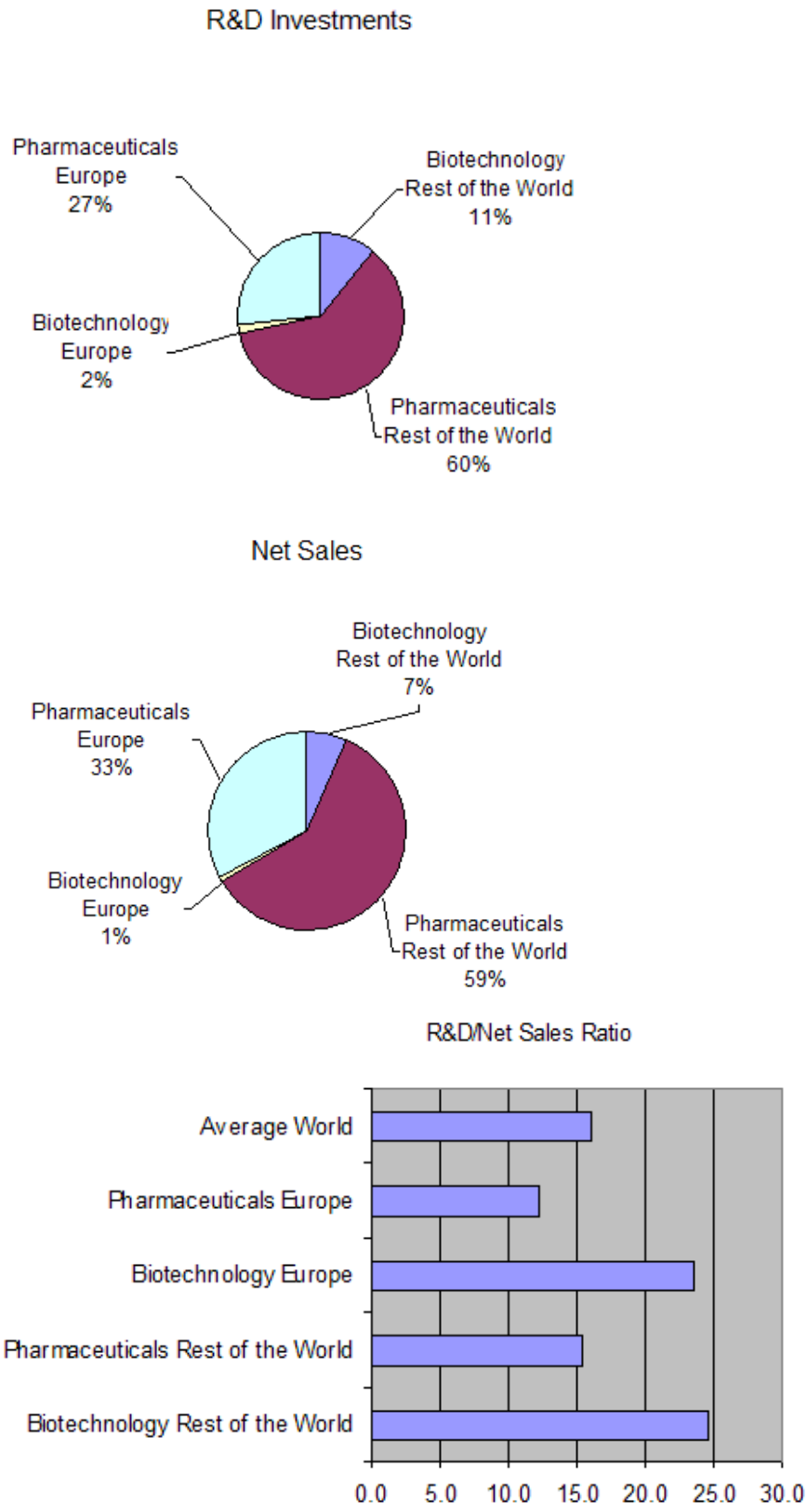
Figure 2: Phases of the R&D process in respect to the length in years. Source: AIFP

Figure 3 depicts volume of R&D investments in particular industries in European Union and classify the Pharmaceutical and Biotechnology industry to be the most challenging.

Sector	R&D investment (million Euros)	Share in R&D investment	R&D/Sales ratio
Pharmaceuticals & biotechnology	71409.8	19.2%	16.1%
Technology hardware & equipment	68154.1	18.3%	8.5%
Automobiles & parts	63234.4	17.0%	4.2%
Software & computer services	26594.7	7.1%	9.7%
Electronic & electrical equipment	26049.2	7.0%	4.1%
Chemicals	16427.7	4.4%	2.8%
Aerospace & Defence	15133.7	4.1%	4.4%
Other 29 sectors	85855	23.0%	24.0%
Total	**372858.6**	**100%**	**3.4%**

Figure 3: Comparison of particular industries in EU. Source: The 2008 EU Industrial R&D Investment Scoreboard, European Commission, own graphical modification

The following figures compare situation in European pharmaceutical market with the Rest of the World, strongly dominated by US.



Figures 4, 5, 6: EU vs Rest of the World. Source: European Commission, modified

Rest of the World with the clear leadership of US and its firms dominanates Europe both in absolute and relative figures of R&D investments and net sales (as well as their ratio).

Another graph compares R&D investments as percentages of GDP and BERD (cumulative Business enterprise expenditure on R&D) in several countries. Czech republic is represented by average values in both indicators, as R&D expenditures in the Czech pharmaceutical industry in 2006 formed 0.13% of GDP and 12.59% of all private R&D expenditures.

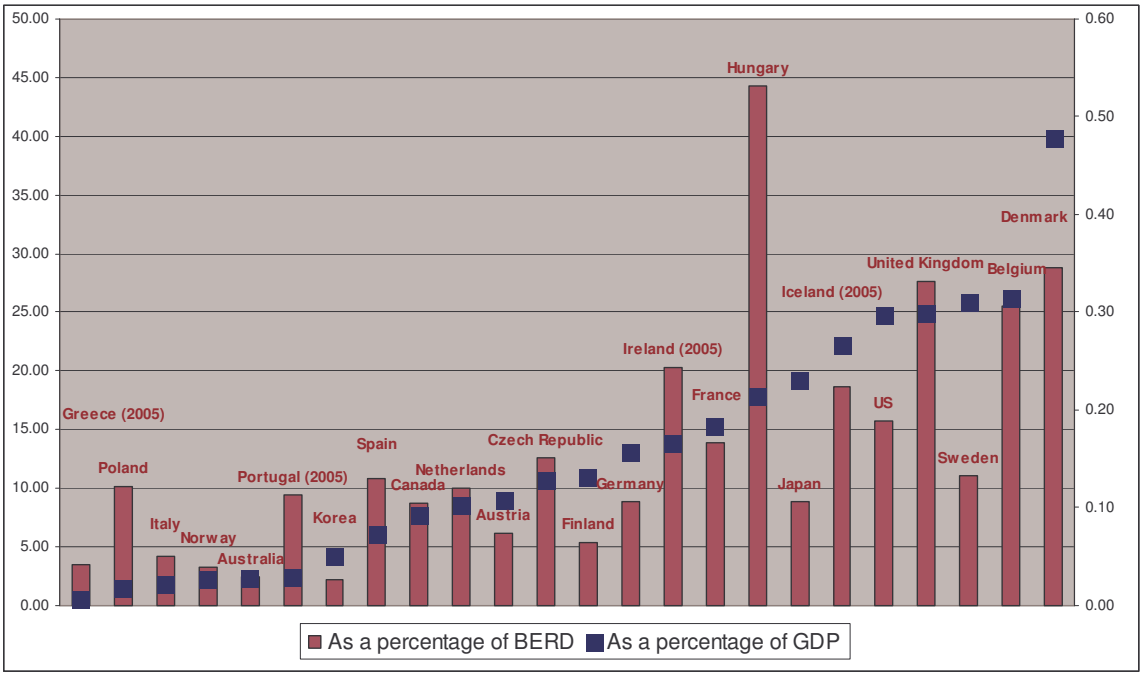


Figure 7: Source: OECD Science, Technology and Industry Scoreboard 2009: R&D expenditure in the pharmaceutical industry as a percentage of GDP and BERD, 2006, own modification

4.2 Phases of R&D and the regulatory hurdles

There are four regulatory hurdles in the process of original patented drug development:

1. Medical and classified regulation

The confirmation the medicine is effective and safe is required.

2. Price regulation

The system of reference countries as well as the system of settlements used in Czech republic and other EU countries are described in Chapter 4.3.5.

3. Prescription limitations

Not all medical doctors are allowed to prescribe anything, there are limitations set by expert committees.

4. Pharmacoeconomics

Pharmacoeconomics tries to find equilibrium of effectiveness and expenses. A willingness to pay determines the compromise between cost and effects. To estimate these values a method of Health Technology Assesment (HTA) is used.

All in all the length, expense and rate of risk demonstrated by high failure rates, costs of clinical trials and resources during new medicines' research and development conducted by pharmaceutical companies along with ethical issues related to sensitive sector of healtcare that bring other expenditures to get approval by relevant authorities are the main rationales for complex industry regulation.

4.3 Regulation in Czech pharmaceutical industry

The reform of the Czech health care from a state-run system of central-planned economy type, which emphasises the availability, to a modern health system of Western Europe type, which points out the quality and efficiency, began in the 90's by implementing compulsory health insurance, substituting financing by taxes. During the transformation, many negative aspects occurred:

- deficit-generating finances of the system
- unbalanced distribution of the deficit among insurance companies

- increasing expenditures: population ageing, new and increasing occurrence of diseases, salaries in the sector

To summurize these aspects, the demand side has been driven by expectations and demographics, the supply side, on the other hand, has been defined by capacity and structure. Both sides influence the resources that are limited by real economy and political decisions.[11]

Moreover, there are several negative phenomenons related to a trade with medications. Even though some of them may be called fictions or myths, they are all worth a consideration:
- risk of drugs' overuse, misuse = unhealthy lifestyle = even higher expenditures
- doctor's visit = drug prescription
- pharmaceutical lobby, moral issues: a high profit at (public) health service, corruption
- public sources are absolutelly crucial

Some of the specific featured areas are already regulated by a government, e.g. advertisement, and other have been regulated by self-regulatory organizations (SROs), e.g. sponsorship of doctors to presribe particular drugs, specialised seminars connected with exaggerated free-time treatment.

4.3.1 Drug's registration procedure: State Institute for Drug Control

Before being introduced to the market, drugs need to get a registration at SUKL.[12] The main tools to minimize predictable risks of introducing a new medicinal drug are substantiating an effectiveness, quality and assuring of harmlessness. The process of approving the registration is based on evaluation of agreement in submitted

[11] Peter Pazitny, Tomas Szalay, Karol Morvay (Health Policy Institute Slovakia): Czech republic: Fiscal study, diagram 1, the Evans equation: Demand = Resources = Supply

[12] Státní ústav pro kontrolu léčiv = State Institute for Drug Control

documentation, up-to-date scientific knowledge, in an interaction of legal directives. There are several types of registration procedures in Czech republic[13].:

- *National:* declining use of the type, forbidden for already registered drugs or drugs in the middle of a process of registration in another EU member state, also forbidden for drugs with compulsory Centralised registration
- *Mutual recognition:* meant for already registrated medicines in a EU member state, the member state accepts the registration procedure run by the reference member state
- *Decentralised:* registration of a drug which has not been registrated in any EU member state, the procedure consists of five stages: preparation, validation, first and second evaluation, National phase
- *Centralised:* a compulsory procedure meant for biotechnologically prepared drugs, recent developed medicinal substances for AIDS indication, oncological diseases, neurodegenerative diseases, diabetes and scarce diseases, the assessment is guaranteed by the European Medicines Agency[14] and the registration is granted by European Commission.

4.3.2 Original vs Generic drug

The distinctive registration methods differ in dependance on a type of a medicine. An **original drug** is produced and distributed under patent protection on the active ingredient which had been registered for the first time. A **generic drug** contains the same active ingredients as the original formulation, but is produced and distributed without patent protection. The main reason for the relatively low price of generics is that competition among producers naturally increases when drugs are no longer protected by patents. Nowadays there is a new phenomenom of producing the generics by their inventor too to cumulate extra finances for further research.

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[13] http://www.leky.sukl.cz/encyklopedie/

[14] According to the wikipedia, EMEA is a European agency for the evaluation of medicinal products. From 1995 to 2004, the European Medicines Agency was known as The European Agency for the Evaluation of Medicinal Products. The official website: http://www.emea.europa.eu/

According to statements of pharmaceutical representatives the reference system (chapter 4.2.4) clearly supports prescribing and using generic drugs. The data published by IMS Health confirm there are regularly twice as much generics than original drugs on Czech market in volume figures although in financial figures the original drugs have twice as big market share as generics. These relations also suggest significant differences in prices of generics and original drugs.

4.3.3 Patents

We have already showed in Chapter 4.1 that the development and subsequent procedure of verifying harmlessness and effectiveness of a drug are expensive processes. Out of 10-20 thousand of developed substances only 5-10 get to the phase of clinical assessments. Finally only one substance of those thousands is registered as a medicine suitable for curing the patients and that is the worlwide rationalization of introducing patent laws. [15]

4.3.4 Price limits

Subsequently SUKL under the supervision of the Ministry of Health[16] specifies the maximum prices, which may not be exceeded by neither producers nor distributors. In the drug price regulation Czech republic helps itself by monitoring the prices of other EU countries which is subsequently used as a yardstick in setting price limits. As of 1st January 2008 the maximum price of producer changed to an average price of the prices in a so-called **reference basket** of countries compiled on the basis of reference countries with similar economic performance. It is based on the premise that medicine prices correspond to the economic power of a country, like the prices of other products. In comparison, the reality shows the paradox that the lowest prices of drugs can be found not in Europe's poorest countries, but in the UK and France. [17] Those prices reflect the

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[15] Source of the statistical estimation: http://www.leky.sukl.cz/encyklopedie/

[16] Till the end of 2007 it was in jurisdiction of the Ministry of Finance, which influence was rather symbolic since it had no tools to verify the justifiability of the specified maximum costs.

[17] Peter Pazitny, Tomas Szalay, Karol Morvay (Health Policy Institute Slovakia): Czech republic: Fiscal study, page 5

size of the market, the competition, the negotiating power of individual sides. Anyway at present the reference countries are: Estonia, France, Italy, Lithuania, Hungary, Portugal, Greece and Spain. If there is a drug not available in at least three of these countries, the alternative of an average price of three lowest producers‘ prices in EU member states is applied. Furthermore, if non of these models is applicable, SUKL uses producers‘ prices of the closest therapeutically similar medicine in Czech republic or in EU. There is the Department of Statistics and Analysis in Prague responsible for determining a suitable model. The responsible team consists of people with foreign language and computer skills. Nevertheless their activities are probably more mechanical and time-consuming than creative.

4.3.5 Price regulation

As mentioned above, The State Institute for Drug Control (SUKL) decides on maximum prices and operates price control of medicinal products, foods for special medical purposes and medical devices. It means that the Ministry of Health issues decisions on prices by which the method of regulation of a product is determined. Key factor of a price regulation is that a medicinal product (medicinal products, foods for special medical purposes and medical devices) is subject to price regulation if the product is fully or partially covered by the national health insurance system. Other products‘ prices can be set by a market, as individuals decide on financing them fully themselves. Price regulation applies to producers‘ (ex-factory) prices and trade margins. It also defines allowance reduction, as a compensation of recently established regulation fee paid for a prescription.

SUKL is the competent authority responsible for setting the maximum ex-factory prices. [18] The method for setting prices has the form of individual administrative proceedings. Proceedings are initiated upon submission of an application. Appeals should be filed with the Ministry of Health.

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[18] SUKL offcial web page for experts http://www.sukl.cz/

Since 1 January 2008 the reduced valued added tax rate has increased from 5% to 9%. Maximum producers (ex-factory) prices and reimbursement levels for medicinal products remained unchanged. However, without introduction of other changes, the consumer prices and consequently patient co-payments would increase by 3,81%.[19] As regards prescription-only medicines, the 4% VAT increase and higher trade margins on cheaper products are compensated by the pharmacy service fee of 30 crowns, for more expensive products it is partially compensated by reduction of trade margins and also from the 30 crowns service fee.

Let us analyse a final price of a drug paid by a consumer in a pharmacy. This would be useful for further consideration of public knowledge and perception of price composition. The final price of a drug is set as follows: maximum producer's price + trade margin (distributor, pharmacy) + VAT – allowance (equation 1)

$$\text{Allowance} = fee_{regulation} * (0,25 * (arctg\left(\frac{p_{producer}}{50} - 2,5\right) + 1,6)) \qquad (1)$$

Where the fee regulation represents the pharmacy service fee of 30 crowns and producer's price is already mentioned ex-factory, producer's maximum price set by SUKL's reference model. In the figure 8 below we can see how the mentioned formula determines a dependendance of allowance, which is subtracted from the total price of a drug, on a price of producer.

[19] Presentation of Martin Mátl (Česká lékárnická komora)

producer's price	*arctg*	allowance
10	-1,16	3,59
20	-1,13	3,87
30	-1,09	4,20
40	-1,04	4,59
50	-0,98	5,05
60	-0,92	5,60
70	-0,83	6,27
80	-0,73	7,09
90	-0,61	8,09
100	-0,46	9,29
200	0,98	21,11
300	1,29	23,65
400	1,39	24,45
500	1,44	24,84
600	1,47	25,06
700	1,48	25,21
800	1,50	25,32
900	1,51	25,39
910	1,51	25,40
920	1,51	25,41
930	1,51	25,41
940	1,51	25,42
950	1,51	25,43
960	1,51	25,43
970	1,51	25,44
980	1,51	25,44
990	1,51	25,45
1000	1,51	25,45

Figure 8: The allowance, MS Excel

The characteristics of function arctangent assure the further the price is from a turning point (where the arctangent from the formula equals zero) the smallest the marginal changes of an allowance are. The turning point in this case is a producer's price of 125 crowns. Therefore, there are only very little changes of it in case of the most expensive drugs. For example, if the producer's price of a drug is 100 000 crowns, the allowance is 25,917, which is really close to the allowance of the producer's price 1000 (25,45). It is more convinient to illustrate it on a graph (again an output of Microsoft Excel).

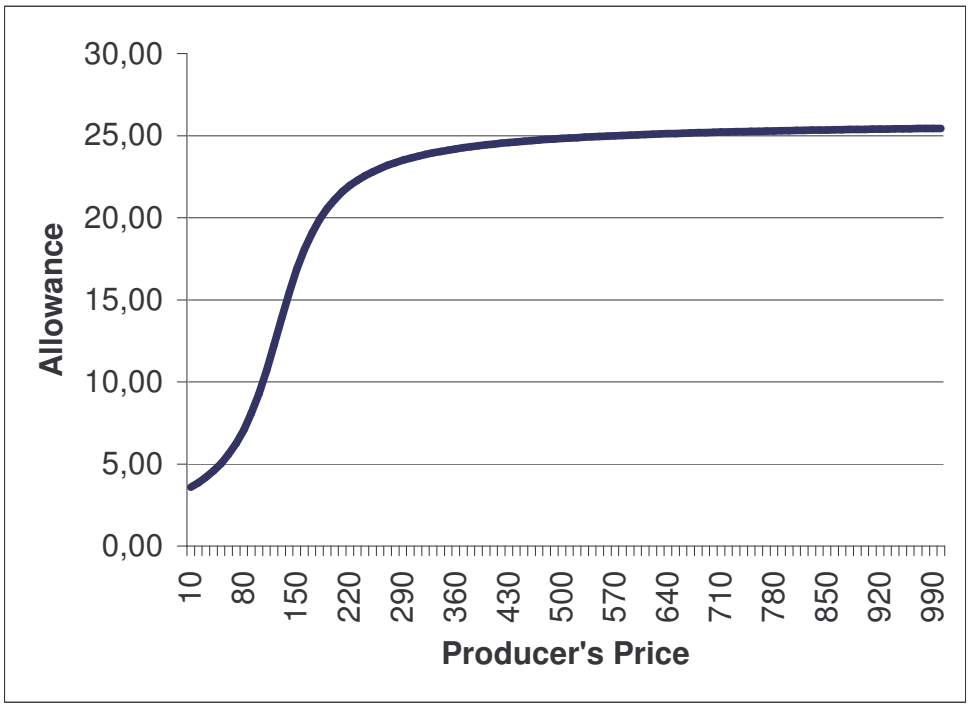

Figure 9: Allowance / Maximum Producer's (ex-factory) Price

4.3.6 Public awareness of drug's price structure

The trustworthiness of self-regulation is directly linked to public perception, which will be described in detail in chapter 8. Therefore public knowledge of basic relations in an industry is neccessary. Based on a survey ordered by ČAFF[20] in the first quarter of 2010 in an advertising agency STEM/MARK (Figure 10), patients are not aware of the actual composition of the prescription drugs prices' structures though the transparency of implemented changes in the system should be the highest priority for the SÚKL. The fact the general public still has not gotten used to a new system is a supportive argument for criticism from the association demanding greater power in creating legislative proposals and systemic changes.

[20] Czech Association of Pharmaceutical Companies (ČAFF, associating producers of generic drugs), for further description please see Chapter 5.3

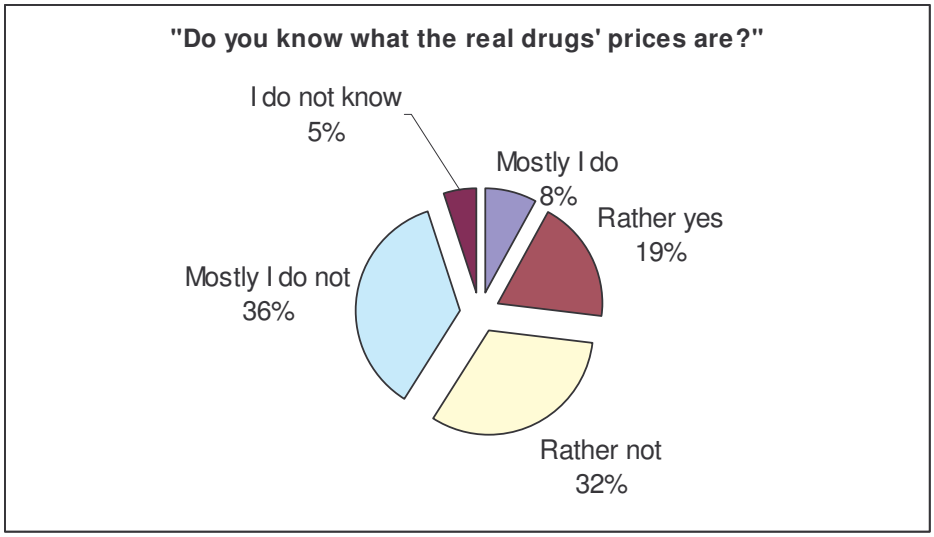

Figure 10: Source of the data: ČAFF and STEM/MARK

Let's have a look at the actual decomposition of the retail price of medicine in Europe (2007).

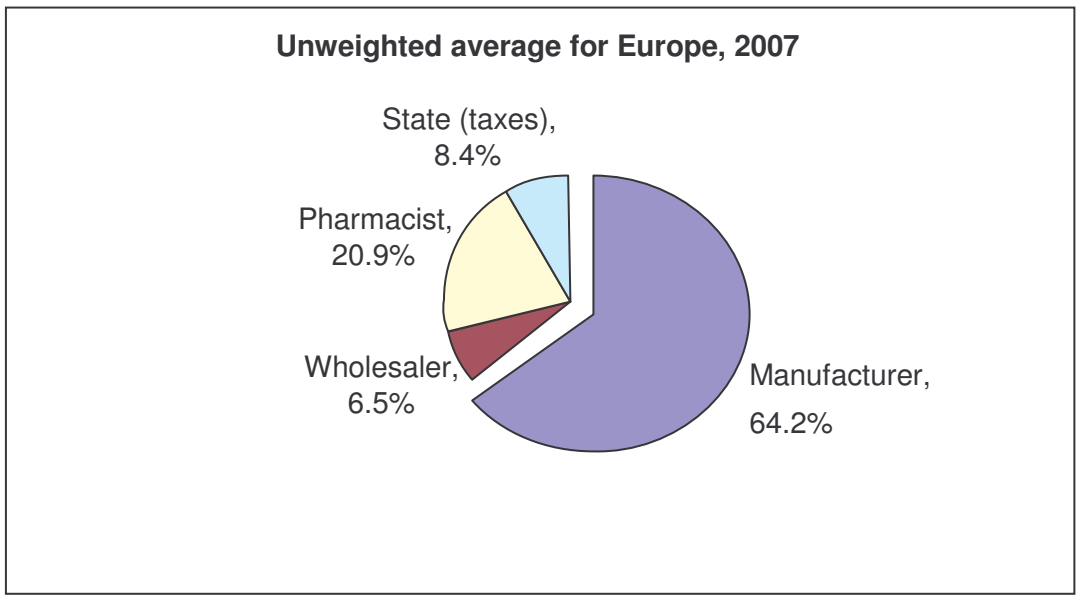

Figure 11: Source: EFPIA and its members associations

5 Institutional alternative of self-regulation and its assumptions

Using empirics, available literature and other sources, knowledge and information obtained during interviews with head representatives of Self-Regulatory Organizations (SROs), this chapter tries to assess the assumptions, preconditions and suppostitions of self-regulatory regime as well as to distinguish between them, taking into consideration previously analyzed specific features of the pharmaceutical industry and the conditions within relevant part of Czech market.

5.1 Two-tier regulation

Let assume, the combination of self and statutory forms of regulation is the ideal structure of the industry regulation. The assumption[21] is based on previous philosophical and economical background, stating the self-regulation within particular industry is better informed and responsive to innovations. Doyle (1997) adds it is more flexible and more likely to ‚*respond to unforeseen events*.' However, he argues there occurs ‚*collusive practices' and "window dressing"* too and only statutory regulation is able to make ‚*sanctions credible*.' Therefore it is always better to implement mix of statutory and self-regulatory regimes – ‚*two-tier regulation'* – as there is a risk of misusing certain specific features of oversights of the government and customers in case of pure self-regulation such as ‚*price-fixing as the SRO itself might not be subject to regulation*.'

It is important to distinguish different types of incentives for self-regulation to arise. In literature, authors introduce an absence of statutory regulation as the motivation of self-regulation. However, the motivation could be ambiguous: either the self-regulatory organization is motivated to urge to avoid constitution of particular statutory regulation[22] or is motivated to introduce non-existing rules that should be enforced and would be beneficial for both firms and customers.

[21] That the model in chapter 9 tries to confirm, concerning the pharmaceutical industry in Czech republic

[22] Or even trying to abolish existing legislation

The fundamental question is defining and choosing the appropriate balance of self and statutory regulation. According to Doyle (1997) and his research and studies, the proportion of both regimes should be in general determined by following factors:

1. *the nature of competition*

   In the Czech pharmaceutical industry there is tough competition of original and generic drugs producers.

2. *the hierarchical structure of firms*

   Hierarchy can be seen on different geographical levels – world, European Union, Czech republic.

3. *the scope of activities undertaken by firms*

   Most of the firms' business activites are already strictly regulated and also monitored by independent institutions.

4. *the pace of innovation*

   The industry attempting to find new and better substances to increase human life expectancy and better its quality is based on innovations = original drugs that are therefore being patented. However, their development is lengthy and expensive process with low success rate.

5. *the availability of information*

   The issue will be discussed later on.

5.2 Assumptions for effective self-regulation

The reasons for two-tier regulation have already been outlined in a verbal description. Therefore now we can introduce conditions for effective self-regulation itself within such a combined regulatory regime.

Doyle (1997) considers the industries with considerable competition to have the best preconditions for self-regulation to dominate over statutory regulation. Reasons are clearly intuitive – there is little probability of creation of monopolistic structure or cartel. More precisely there should be defined relevant market by a SSNIP test and found out

there is a huge difference between original drugs protected by patents and generic drugs. However, both types are already strictly regulated in ways discussed in previous chapter. On the other hand, in terms of ethical principles, there is a tough competition in pharmaceutical industry. As most of producers have international field of activity, those on the Czech market are not exceptions.

Blumrosen (1983) based the formulations of '*Six Conditions for Meaningful Self-Regulation'* on experience from failure of voluntary compliance (1940-1964) and its success (1964-1980) in the field of US employment discrimination law.

1. *The standard must be established by law, balancing private needs with the public interest*
2. *A vigorous enforcement program must exist to provide incentives for self-regulation*
3. *The results to be achieved must be measurable*
4. *There may be residual liability to individuals*
5. *Administration and interpretation must support and encourage self-regulation*
6. *There must be sufficient and organized public concern*

All in all, intensive public concern and statutory control mechanisms are main agreements of different authors fot achieving an effective self-regulation.

6 Ethical codes

Current issue delegated on self-regulatory organizations (SROs) in Czech republic is the area of ethical codes of coducts of pharmaceutical producers that is an accustomed practice all over the Europe.

Although football players and fans are often in anger or disagreement with referees they would not prefer to watch and play football without them. Everyone on the pitch would have to take an advantage of nonexisting enforcement of rules. If a player followed them

anyways others would soon take advantage of that decision. Crowd would probably want their favourite players to do everything possible to win, even if that means injuries. In the end the match would most likely resemble completely different type of sport or possibly even war and fans would not be excited anymore but no one would retreat all from a sudden. In such a situation there could be created a code including set of rules and ethical standards. Unless there is a match with an official referee this code would have to be based on voluntary acceptance and therefore would need to acquire most of the players including the captains of both teams. Both alternatives of official rules and referees and unofficial ethical code need to be accepted by fans too as without the interest of public, there would be no conditions for professional sport such as financial sponsors.

Sensitivity of public perception is determined by extent of personal experience and interest of media coverage. In general, public feels that many professions could do more to avoid and eliminate distinctive forms of inappropriate behaviour and actions. Is the general belief of power of ethical codes of conduct to make positive contributions to efficiency and morality reasonable? Already Molander (1987) argues the markets would be *'more efficient and free to work unobstructed to achieve both economic and social benefit'* with reasonable stated ethical codes. The author rationalizes the arguments using ideas of economists Kenneth Arrow and Christopher Stone who belong into the group of those in favor of free market and simultaneously justifying existence of such tools as ethical codes which clearly are sort of restrictions in the free market. Those could be summarized in three reasons of prefering self-regulatory codes to the statutory ones:

1. *'the cost of enforcing laws is too great'*

If the informational barier is too deep to overcome and government would enforce the inaccurate and less relevant rules spending too much money ineffectively, the optimal way is to delegate the authority on a SRO or simply to let the SRO deal with the problems and do not intervene unless it is necessary. For formal description please see chapter 9.

2. *'the enforcement of laws would require the violation of higher values in the society'*

Another justification of delegating the regulatory power is ideological. If government prefers to let the market act in a natural way by its own it is more likely to let the companies decide whether to voluntarily associate into SRO or choose another way of monitoring competitors' activities. Even if companies decide to behave in discrepancy with good manners and public welfare would suffer.

3. *'norms for behavior or ethical standards cannot be translated into objective, adjuducable, legal standars'*

It is often practically not feasible to systematically formulate all the situations that need to be covered by ethical code. Therefore logical existence of legal obstructions would be probably counter-productive, causing the deterioration of credibility of the companies trying to take advantage of legal imperfections to avoid criminal penalization. On the contrary, ethical code compiled by competitors themselves may be more general but still much more relevant, based on first-hand informational advantage. The enforcement is conducted also voluntarily by motivated competitors and consequences are more reputational than criminal.

Molander (1987) as well as Kaye (1996) a decade later continues with distingushing different approaches towards ethical codes determined by different perspectives. The incentives of particular participants at the relevant market naturally differ. The ***individual business manager*** perceives the potential benefit based on possibility to '*clarify company policy in areas of ethical uncertainty*,' contribute to solving *'fundamental ethical dilemmas, resist unreasonable and unethical requests from superiors, customers and others and'* create an image of '*ethical working environment'*. From the ***firm***'s point of view, benefits of the code include '*elimination of unwanted'* practices with negative consequences, '*promotion of new practices'* with positive impact, relief for executives to make some of the '*complex decisions'* regarding covered issues, making '*the detection and enforcement'* of rules cheaper and easier, promotion of good and transparent relationships between employers and their superiors. Going even more global, the

industry prefers setting own code to statutory regulation ordered by the government. From the point of view of whole industry within a country, the code may also prevent practices that would have negative impacts on all its members[23]. From the perspective of the ***business system*** itself, codes contribute to improving reputation of the relevant market and '*restoring public confidence in business'*.

Another crucial task is to determine whether there is potentially a better enforcement of ethical code on a company or industry level. Naturally, both levels can be combined. Firstly, let's distinguish advantages of one type over another one based on different aspects of its enforcement. Although the power, authority, access to information leading to detection of violation, effective and strict punishments are the advantages of enforcement on a *Company-level*, there is risk of ignorance of rules in situations when it is not convinient for the company or its management to take an action or to prefer possibility of profit-making to ethics-enforcing. In such situations there is the enforcement on an *Industry-level* preferred. It also tries to formulate rules beneficial for all industry members and worries less about situation in other industry firms. Such rules are uniform for all the industry members and most likely maximize effort to detect the fraud, even though informational restrictions often occur. The mentioned advantages are summarized in the following table (Figure 12).

[23] Such as bribes that would lead to moving business to another country

	Level	
the relationship to enforcement	*Company*	*Industry*
power and authority	◯	
uniformity		◯
access to information	◯	
profits vs ethics conflicts		◯
detection of rules violations	◯	
worries over other industry firms behaviour		◯
definition and administration of penalties	◯	
ignorance of rules violations		◯
benefit for all industry members		◯

Figure 12: Company vs Industry level enforcement of ethical code: comparison inspired by Molander (1987), the better solution for particular variables determining its enforcement is marked

Rule enforcement, already successfully implemented in Czech SROs' codes, includes detection of violation, reaching the agreement of violation by a specialized comitee and enforcement of appropriate penalties. Those should be token amounts and Czech representatives agree. If they were substantial, an employee would quit which is an effective punishment or a firm would withdraw from the code or association that obviously weakens the code or association itself, especially if the firm has relevant market share or if more firms decide to quit. On the other hand, on the industry-level there is present a significance of public condemnation which cannot be expected in the company-level enforcement.

The requirements for an ethical code that is likely to positively contribute to industry behaviour as well as the public trust in the industry: '*a well-written, reliably and fairly enforced, eliminating unethical practices, relieving ethical dilemmas, motivating firms to effort to ethical conduct.'* On the other hand, if code is '*poorly designed and implemented,'* there can be expected negative effects like '*reducing business credibility even more*.' To sum it up, those are the main queries to assess in the Czech reality before eventually recommending other spheres to deregulate.

Mentioned characteristics of ethical codes are well-known and implemented by Czech SROs too. They prefer the sanction for violation of code to be a symbolic special membership fee, the code itself to be easily comprehensible, not neccessary examining all possible complex situations but rather setting preconditions for evolving ethical business environment. Public awareness of individual responsibility and shame of industry members and high significance of membership are the main goals for SROs to improve. The overall perception of corruption in the Czech society seems to create another vicious circle. According to all available surveys, conferences and Transparency International's reports dealing with it over past few years including these years the ethicality of business environment is doubtful as entrepreneurs are convinced it is inconvinient to report corruption and majority of biggest corrupted tenders is connected to government itself. Public perception of the problem is similar as it does not consider neither politicans nor police investigators trustworthy enough. Given the situation even if the credibility of self-regulatory associations is questioned the statutory regulation does not seem to be an effective option to rely on. However, by commiting unethical act a firm learns how to do that more effectively and profitably and therefore supports further violating. There is more precise analysis provided in chapter 8.

Czech SROs definitely declare the membership to be kept voluntary. However the subject of their interest is to gradually increase their impact in desicion-making process of the statutory institutions which can be only done based on positive experience and gradualistic patient approach.

7 Institutions of self-regulation and its members

If the thesis aims to study the issue in a precise complex way it is evitable to discuss particular subjects and objectives of the self-regulation: what has been self-regulated and cons if it is violated.

7.1 European Union level: EFPIA

Self-regulatory rules within European Union are being formulated and enforced by European Federation of Pharmaceutical Industries and Associations (EFPIA). Through the membership of 32 natinal associations, there are approximately 2200 pharmaceutical companies, including 43 biggest companies, represented by EFPIA.

FULL MEMBERS		
Abbott Laboratories USA	Genzyme USA	Roche Switzerland
Almirall Spain	Gilead Sciences USA	Sanofi Aventis France
Amgen USA	GlaxoSmithKline UK	Schering-Plough USA
Astellas Pharma Europe UK	Grünenthal Germany	Servier France
AstraZeneca UK / Sweden	Ipsen France	Sigma-Tau Italy
Baxter USA	Johnson & Johnson USA	Solvay Belgium
Bayer Healthcare Germany	H. Lundbeck Denmark	Takeda Japan
Biogen Idec USA	Menarini Italy	UCB Belgium
Boehringer Ingelheim Germany	Merck Serono Germany	Wyeth USA
Bristol Myers Squibb USA	Merck & Co USA	AFFILIATE MEMBERS
Chiesi Farmaceutici Italy	Novartis Switzerland	Bial Portugal
Daiichi-Sankyo Europe Germany	Novo Nordisk Denmark	Bracco Italy
Eisai Japan	Orion Pharma Finland	Elan Pharmaceuticals Plc Ireland
Eli Lilly & Co USA	Pfi zer USA	Otsuka Pharmaceuticals Japan
Laboratorios Dr Esteve Spain	Procter & Gamble Ph. USA	Recordati Italy

Figure 13: EFPIA Member Companies

7.2 National level

In Czech republic, there are three main organizations voluntarily associating producers of medicines in order to more effectively communicate with a government and monitor each member‘s ethical and unethical behaviour. Although only one of them is a member of EFPIA, if we compare the rules, structure and strategy of all of them to be similar, it will confirm necessary assumptions to examine the self-regulation in Czech republic uniterally. This chapter introduces them individually providing an overview of their official roles and lists of members. As already mentioned, primary interest is to evaluate whether contents of particular ethical codes are de facto similar and consistent and subsequently whether the aggregate market share of companies voluntarily associated in the three organizations is sufficiently high to effectively implement self-regulatory practices enforcing the code in the whole industry, even among the non-members.

Association of Innovative Pharmaceutical Industry (AIFP, associating producers of original drugs)

AIFP associates 31 members[24], with aggregate 55% market share[25], the producers of original drugs, with their own research and development of innovative pharmaceuticals.

ABBOTT LABORATORIES	BRISTOL-MYERS SQUIBB	NOVARTIS
ACTELION Pharmaceuticals	CELGENE	NOVO NORDISK
AMGEN	ELI LILLY AND COMPANY	NYCOMED
ASTELLAS PHARMA	FERRING	PFIZER
ASTRAZENECA	GENZYME	PIERRE FABRE
BAYER	GLAXOSMITHKLINE	SANOFI-AVENTIS
BEAUFOUR IPSEN PHARMA	JANSSEN-CILAG	SCHERING-PLOUGH
BERLIN-CHEMIE MENARINI GROUP	LUNDBECK	SERVIER
BIOGEN IDEC	MERCK SHARP & DOHME	STALLERGENES
BOEHRINGER-INGELHEIM	MERCK-SERONO	UCB
	MUNDIPHARMA	

Figure 14: AIFP members

Czech Association of Pharmaceutical Companies (ČAFF, associating producers of generic drugs)

ČAFF associates 23 members with over 20% market share with unique members that all differ from AIFP members, according to IMS Health in 2008 there were 63% of all drugs packages distributed to Czech patients originated in member companies of ČAFF.

Actavis CZ a.s.	Richter Gedeon
Apotex (ČR), spol. s r.o	Sandoz s.r.o.
Ardeapharma a.s.	STADA PHARMA CZ s.r.o.
BELUPO léky a kosmetika, s.r.o., organ. Složka	Teva Czech Industries s.r.o.
Chauvin Ankerpharm GmbH, organ. složka	Teva Pharmaceuticals CR, s.r.o.
Egis Praha, spol. s r.o.	Torrex Chiesi CZ, s.r.o.
Ewopharma, spol. s r.o.	Ústav jaderného výzkumu Řež a.s.
KRKA ČR, s.r.o.	VALEANT Czech Pharma s.r.o.
Medicom International s.r.o.	VUAB Pharma a.s.
Orion Oyj, organizační složka	Wörwag Pharma GmbH, organ. složka
PRO.MED.CS Praha a.s.	Zentiva k.s.
ratiopharm CZ, s.r.o.	

Figure 15: ČAFF members

[24] Since March 1st, 2010, when Mundipharma became an official member
[25] In ex-producer prices, source: SRO representatives based on conclusions of IMS Health

Association of producers of OTC drugs[26] *(SVOPL, associating producers of drugs that can be sold directly to a customer without a valid prescription)*

There are 13 members in SVOPL and not all of them are unique as some of them are members of AIFP or ČAFF as well.

Bayer, s.r.o. Health Care	**Sandoz, s.r.o.**
Boehringer Ingelheim, spol. s r.o.	**TEVA Pharmaceuticals, s.r.o.**
GlaxoSmithKline, s.r.o.	**Urgo Medcom**
IBI, spol. s.r.o.	**Wyeth Whitehall, s.r.o.**
Johnson & Johnson , s.r.o.	**Walmark, a.s.**
Merck spol.s.r.o.	**Zentiva Group, a.s.**
Reckitt Benckiser Healthcare	

Figure 16: SVOPL members

7.3 SROs on the Czech market: conclusion

According to IMS Health, there are about 300 pharmaceutical producing companies at Czech market and only 61 of them are voluntarily associated in one of three dominant SROs. However, their market share exceeds 84% and only a big number of small companies decided to stay out of them so far. Their rationalization for decision not to join any SRO does not necessary include intention to violate the self-regulatory rules without being punished. As we will argue later, that would cause them rather loss than a positive payoff. That means there are other objective reasons for staying out. Intuitevely, one of them could be transaction costs of membership as membership fee and attending regular meetings.

7.4 Code of Conduct and its enforcement

The rules have to be as simple and clear at the same time as possible. The commission authorized by the SRO members then decides whether the ethical code has been broken

[26] Over-the-counter

or not. We provide detailed comparison of their structures since all SROs have defined their own codes of conduct:

AIFP	ČAFF	SVOPL
Nature and availability of information and claims	Nature and availability of information and claims	
Product information	Product information	Product promotion
Promotional material	Promotional material	
Medical representatives	Medical representatives	Medical representatives
Product samples	Product samples	Product samples
Trade displays	Trade displays	
Sponsorship of traveling and meetings	Sponsorship of traveling and meetings	
Other sponsorships		
Research	Research	
Relationships with healthcare professionals	Relationships with healthcare professionals	Relationships with healthcare professionals
Communication to the public	Communication to the public	

Figure 17: Codes of conduct comparison

As we can see there are no big differences in the areas covered by ethical codes. The reason for some missing parts in codes of SVOPL and CAFF in comparison with AIFP is there are different kinds of pharmaceutical producers associated in different Czech SROs.

As already discussed, the sanctions have to be symbolic expecial membership fees and the real threat should be a threat of damaging reputation and taking responsibility of the national management in a relationship to international management in case of most spread - international companies.

AIFP + ČAFF	*violating the code*	SVOPL
Reprehension	*slight violation*	Reprehension
50k Kč	*mild violation*	max. 20k Kč
100-200k Kč	*serious violation*	max. 50k Kč
300k Kč	*repeated violation*	max. 100k Kč

Figure 18: Internal penalties, comparison

In reality, every year there are several complaints made, most of them are accepted as code violations by the commitee and then punishments are being enforced.

8 Modelling the Informal regulation in presented settings

After discussing general background providing main features of examined relevant market and assumptions for an effective self-regulation and their comparison with the reality within Czech pharmaceutical market, it is tenable to define a theoretical concept - a model that would help evaluate the situation more precisely. The social inefficiency of unethical behaviour clearly stems from the requirement of both drug and doctor's decision being of lower quality. The main concern is to confirm SRO's[27] ability to be effective which is directly determined by firms' incentives to enforce industry ethical behaviour and governmental incentives to further deregulate or continue with deregulation of particular features of the industry.

Let us first have a look at the possible approaches defined in the existing literature. Most of the literature assumes the industry self-regulation to be initiated by government and enforced at the particular industry level. However, there are cases when it is initiated by industry participants themselves which is the case of Czech associations of medicine producers. The reasons for such development can be empirically deduced. Primary reason is intuitive: the formulated rules had never been in practice before. In other words, market

[27] Self-Regulation Organization as defined in chapter 1.1

players felt not just that they could solve particular problems more effectively than government, but that they would all be better off with the new rules. To confirm their honesty it is suitable to set the hypotheses and test them. The main goal of this chapter is to construct a partial theoretical model of self-regulation based on findings concluded within previous chapters that would specifically confirm the incentives' sufficiency and estimate trends in Czech pharmaceutical industry. Theoretical concept developed by discussing pros and cons of those concepts covered within existing literature and author's own consideration is connected with empirical contribution to the model consisting of verbal analysis. It is a bearing part of the chapter as the access to relevant data is considerably limited.

The following table illustrates all players of the relevant regulatory framework we have already discussed. However, the mediators between firms and customers cannot be overlooked here as they are important factors of actual decision-making process of customer preferences – patient needs.

EU	EMEA	EFPIA	Producers through national SROs	
Level	**Government**	**SRO**	**Firm**	**Customer**
Czech republic	SÚKL	AIFP ČAFF SVOPL	*Producers* Original drugs Generic drugs OTC drugs and supplements	*Patients*

Figure 19: National and EU level of discussed topic

The content of self-regulation itself has been already discussed in chapters 6 and 7. Hence it is suitable to simplify the effort of enforcing ethical codes to avoid **bribes from drugs' producers to doctors that prescribe them to the patients**. Therefore the first step is to show the consequences of corruption itself using simple demand-supply model, assessing motives of doctors as potential bribe takers and firms – producers as potential bribe payers. Subsequently, we need to show the convenience of firms' ethical behaviour to justify incentives for voluntary self-regulation and to combine them with specific features of Czech pharmaceutical industry and active statutory regulation. As there is a self-regulatory organization (SRO) established by firms themselves, the chapter fully

concentrates on their main incentives. However, there is plenty of literature concluding decision-making incentives of the SRO itself and it would be counter-productive to ignore such complex efforts. As we will see later, the possibilities of exposing fraud and enforcing the rules effectively or not and increasing power of SRO itself have substantial impacts on the firm's behaviour as well. Finally there should be at least brief discussion of determinants of willingness of the government to delegate responsibility for more effective regulation as well as the comparison with regulation under more intense statutory interventions[28].

Once again, the first step of the applied theoretical modeling is to generalize unethical conduct of drugs' sellers towards the doctors in the following way: Pharmaceutical companies (sellers and potential bribe payers) motivate the doctors (potential bribe takers) to preferentially prescribe the drug they developed and produced to the patients (buyers, customers) through provisions, unethical extent or form of sponsorship or any other form of direct and indirect bribes (bribes, corruption).

8.1 Bribe takers and payers in general

The model starts with analyzing effect of an unethical behaviour from the point of view of doctors as potential bribe takers. Let us consider per unit bribery that a firm pays the doctor to promote presription of some of the medicines. Then linear supply and demand model can be inspired by tax-model of Hayford (2007).

The supplied quantity is $Q^S = a + b(P - X)$

The demanded quantity is $Q^D = c - dP$

where a, b, c, d are parameters, P is price per unit and X is bribe per unit.

Then setting the supplied and demanded quantities into equilibrium ($Q^S = Q^D$) we get the price that patients as buyers pay:

$a + bP - bX = c - dP$

$P(b + d) = c - a + bX$

[28] Reference-countries system, original vs generic drugs

$$P^* = \frac{c - a + bX}{b + d} \tag{2}$$

and the amount the sellers receive:

$$P(b+d) - bX - dX = c - a - dX$$

$$P(b+d) - X(b+d) = c - a - dX$$

$$P^* - X = \frac{c - a - dX}{b + d} \tag{3}$$

Therefore the equlibrium quantity is

$$Q^* = c - d\frac{c - a + bX}{b + d}$$

$$Q^* = \frac{ad + bc - bdX}{b + d} \tag{4}$$

The effect of imposing bribes is denoted in the figure 19 finalizing the contribution of demand-supply model to our study.

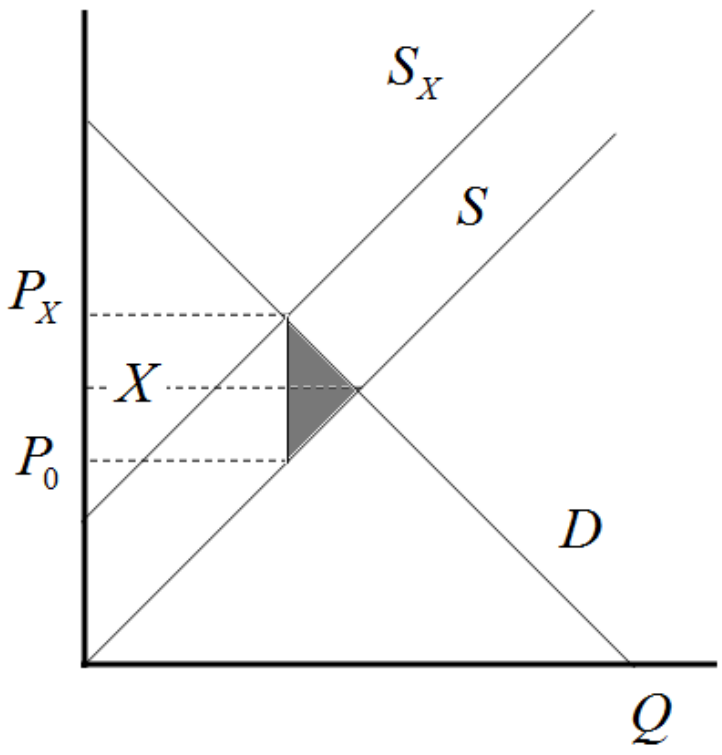

Figure 20: Dead weight loss of corruption

There obviously occurs a dead weigth loss volume that can be then computed using previous equations as $\frac{bdX^2}{2(b+d)}$ which is increasing quadraticaly with increasing corruption level.

8.2 Bribe takers and payers in our settings

However, this simplified draft of supply / demand model ignores specific features of Czech pharmaceutical industry that can be concluded from the previous chapters. A consumer (patient) is mostly not the one directly choosing the products as a medical doctor makes a prescription based on his knowledge and experience and pharmacist has the possibility to offer a substitution of the prescribed drug with a cheaper generic alternative. The consumer may also not be the one directly paying the full price of product as there is supplementary insurance in practice and most of the presribed drugs are fully or partially covered by the insurance company.

Moreover, the chapter 4 describing R&D of a new drug showed the costs of producing already developed drug are negligible in comparison with the costs of its development and registering process. Let the supply curve's elasticity be then infinite as the price is restricted by reference pricing regulation that take into consideration lowest prices in European Union and therefore there is no suply at lower price available. Let the demand curve be perfectly inelastic as patients are dependent on decisions of their prescription doctors when having health problems. The equilibrium in an ethical environment is the intersection of S and D_0 (Figure 21). Let us consider a particular medical substance present in two drugs that have been assessed to be generic substitutes, offered by two different producers A and B. The producer A decides to bribe doctors to prefer his product. Prices of both producers have to remain the same because of existence of reference pricing system and generic substitution discussed below. If the producer A increased the price, a pharmacist would have to inform a patient about existence of a cheaper alternative. The effect of corruption is moving demand function for a producer's

A drug D_A right and simultaneously moving a demand for a producer's B drug D_B left as there is limited total demand for a particular type of drug.

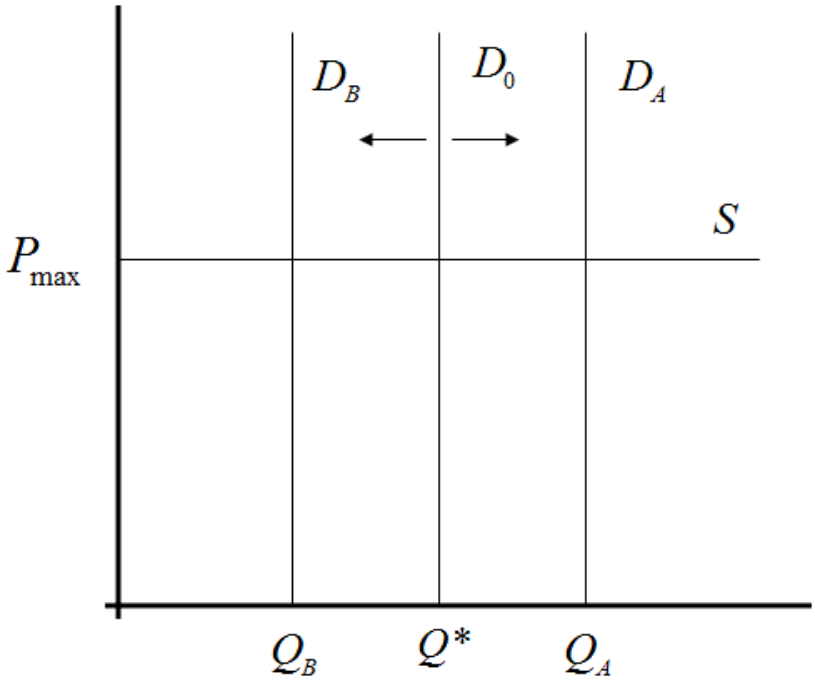

Figure 21: Modified demand-supply model

Based on previous experience and economically justifiable reasons, expected reaction of a producer B is then bribe a doctor as well, not to be gradually eliminated. With first occurance of bribery, the firm A would be in competitive advantage ahead of firm B, which means an increase in sales, which is naturally unstable situation where another firm would bribe in greater extent trying to regain dominant position itself.

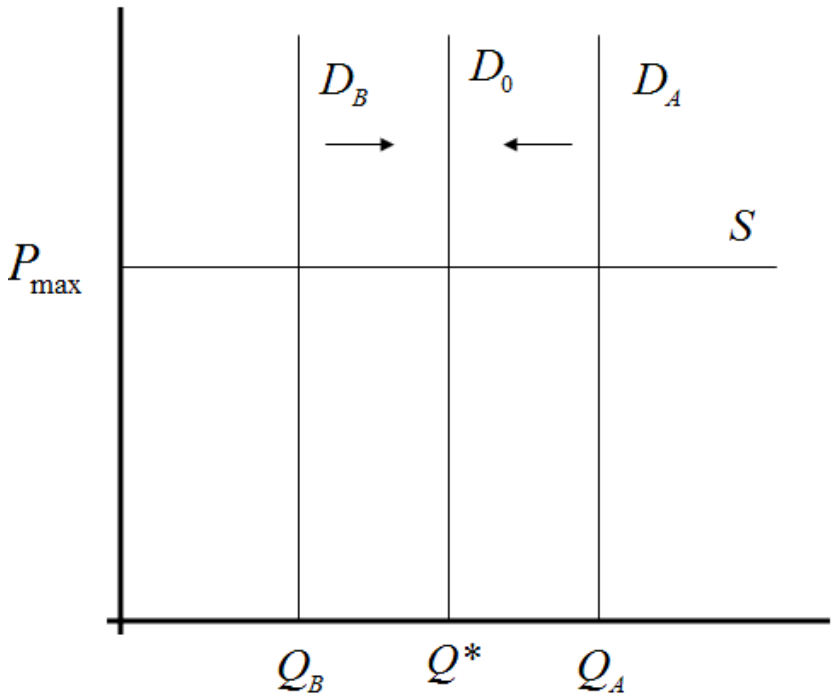

Figure 22: Unstable situation of unethical conduct

The final equilibrium would theoretically correspond to the original one, but what would the costs of its attaining be and who would in fact bear them?

8.2.1 Bribe payers and their profits

Let us define the simplified profit function for a particular firm:

$$\pi = Q(P - C - X) - p(X)L \qquad (5)$$

Where price P is fixed, total costs of introducing a drug to the market per unit C can vary dependently on a quality that is negatively correlated with per unit bribe X. In case of positive X, there exists a probability $p(X)$ of its detection and subsequent punishment L to the bribe payer.

The firm's bribery payoff is then directly determined by relationship between possible ΔCQ and corresponding corruption plus penalty $XQ + p(X)L$. Based on information provided in chapter 4, thanks to strict regulation and specification of the whole R&D process it is almost impossible to significantly lower the costs by lowering quality, like it would be possible in other industries. Although the unethical conduct does not payoff directly, there is still a concern of $p(X)L$ to be too low to prevent every firm from trying to gain more significant market share and therefore to prevent further spreading of corruption.

In case of exposure to the public, by a competitor, media or other monitoring institution or individual, a firm that violated rules automatically faces external penalty L that consists of a loss caused by reputation damage either because of public perception or by suspension from different associations. Another important factor is high level of self-regulatory awareness in countries where the pharmaceutical firms have their origin or a greater sales turnover than in Czech Republic (e.g. Sweden, Great Britain, US). As a consequence local directors are significantly motivated to follow the rules which are broadly consistent and in most of the issues almost identical[29] with those in countries where the board of directors has to be truly aware of reputation. Therefore with violationg the rules, local directors risk their careers by risking the company's reputation. To sum it up there is significant role of so-called compliance officers denoted for an inner audit in company's headquarters. L may also include costs of eventual legal trial as a consequence of a fact some of the rules of ethical conduct and government laws are identical.

Origin of unstable equilibriums and reducing the attainable profits mean inconvenience of unethical behaviour for both firms and form the basic motivation for the ethical behaviour in the whole industry with the necessity of volutary accociating in SROs.

In case of existence of SRO associating firms willing to explicitly follow written ethical standards, the profit function of a SRO member is an extension of (5) and looks like this:

[29] There is a detailed comparison in chapter 7

$$\pi = Q(P - C - X) - p(X)\left[(p_e - p_b)(L + T) + (1 - p_e)T + p_b(B + T)\right] \quad (6)$$

p_e is a probability of fraud exposure to the public, in such a case, internal penalty has to be imposed as well. 1- p_e is a probability of covering the fraud up by SRO which has detected it. p_b is a probability of situation when SRO is willing to expose the fraud to the public, but does not expose it as a member successfully bribe it to cover it up and avoid external penalty. The crucial question to be answered is how to increase p_e and therefore decrease hiding the detected fraud from the public perception. The answer seems to be simple as SRO consists of competitors that associate voluntarily and know that covering up frauds would again lead to the spreading of ineffective bribery mechanism. However, let analyze newly defined segments of penalties to unethically behaving firms in more detail having in mind existence of SRO that has an informational advantage ahead of the public as it is formed by pharmaceutical producers themselves.

In our case, except from representatives from firm A and B there are other representatives who are experts in an industry and regulation forming SRO and its council decising whether code of conduct has been violated or not. After the SRO detects violation of the ethical code there are several possibilities of punishment towards the offender dependent on whether SRO decides to expose the violation to the public (p_e - p_b) or not (p_n + p_b). The offender might face the one or combination of punishments depicted in Figure 23.

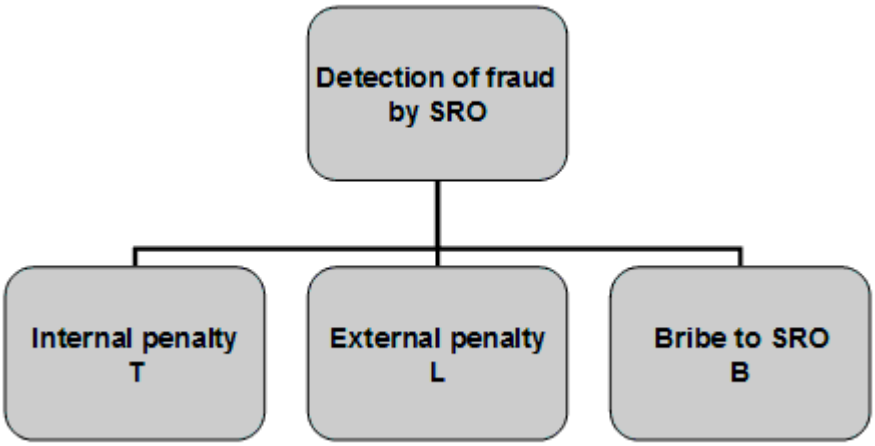

Figure 23: Three possible financial consequences to a bribe payer in defined settings

As there are particular intervals of charges established in the code of conduct determined by the seriousness of violation, if it is revealed, SRO penalizes the violator also with an internal penalty T. This penalty is however imposed independently on whether the violation was exposed to the public or not. Another aspect is the public does not have direct access to the information related to the particular cases. Based on the relevant literature as well as the experience of Czech's SROs representatives, too high T could discourage members to take part in self-regulatory association and leave the SRO. If the significant share of market participants is not explicitly accepting the self-regulatory rules by associating in SRO carrying incentives supporting ethical conduct are disputed. In case of high T there emerges also an increase of incentives to establish collusive agreements within the SRO (cover-up, impunity, then often higher levels of fraud).

Therefore there need to be variables determining optimal T such as L, market size and power, social level of corruption perception, and others taken into consideration. As will be discussed in part 5 of this chapter, there are several incentives of SRO and its members not to expose the fraud publicly. However, even if there is no exposure to the public, the internal fine still needs to be noted in financial report visible to the headquarters that would probably take resolute steps towards national-level management as prevention.

'*The member can pay the SRO a bribe B in exchange for a cover-up in order to avoid L*' (Nunez (2007)) before the decision about unethical conduct's exposure to the public is made. There has to be a cost of such an unconventional decision taken into consideration. Important point is specific to our case, where the members themselves are the ones keeping their competitors' conduct under strict and intense surveillence, reporting most of the suspicions and forming a council that decide whether the code has been violated or not. In those cases this type of bribe seems to be unprofitable without further formalisation. There remains the risk of bribe to SRO in case the administration of organization itself is the one that revealed the violation. In this case an offender has to try to bribe SRO even before the act is forwarded to the council and it would mean a serious risk for a SRO to lose the trust of other members. To sum it up, competition between different SROs should be noted too.

8.2.2 Doctors as key decision-makers

Another issue that can be answered based on previous discussion includes the conditions of environment's corruptibility among doctors as mediators of the whole decision-making process. As there is considerable information asymmetry between producers and consumers, mediated and determined by decisions of doctors and pharmacists, medical drugs are considered credence goods. Such a situation supports high reliance on doctors' decision-making. On the other hand, if patients gain sufficient experience with a particular brand they are tending to be more loyal to that brand in the future. Klemperer (1995) argues the patients prefer the re-usage of those drugs that worked in the past to those that are newly introduced due to lack of empirical information. In the environment of unethical conduct the brand-loyalty is even more probable to be widespread. There are three main practices implemented also in Czech republic to prevent inefficient prescriptions and too intense brand-loyalty:

1. generic substitution
2. reference price system
3. increasing awareness of patients

Generic substitution provides the patients certainty to be informed about substitutes for the prescribed medicine, usually substituting original brand drug for a cheaper generic drug. All in all, the idea is to provide patients as much information as available and to save both public and personal funds. However many professionals argue there is a threat of insufficient treatment when preferring cheaper drugs. Although the main substance is the same, additional substances and methods of their testing may differ. On the other hand without the generic substitution there could be a lot more cases of prescribing more expensive drug than needed and no alternatives to choose from.

Reference price system sets maximum prices derived from prices in countries within reference basket[30] based on a medicinal substance and therefore favors cheaper generic drugs. The generic substitution itself has significantly lower economic importance when reference pricing is already in practice.

Both generic substitution and reference price system undoubtedly promote usage of generic drugs as substitutes to original brand drugs. However their consumption is inevitable not only because of their more trustworthy quality but also because of supporting further R&D of new medicinal substances. Without original drugs there would not be generic drugs and without generic drugs there would not be efficient competition. Therefore both types of drugs are needed and there already are companies producing them both at the same time.

In such a framework public awareness seems to play crucial role. Along with the possibilities to choose substitutes of drugs and to choose the doctor they can trust, the consumers have better access to information over time. Already Matthews (2001) indicated the *physician-directed system* to be transformed to *patient-directed system*. The significant impact of easier access to information on active role of patient in decision-making process is empirically confirmed by several papers, e.g. Merino-Castello (2003).

[30] For more detailed description please see chapter 4.3.4

Increasing public knowledgeability could also increase elasticity of demand over time, which we considered to be zero.

8.2.3 Bribe takers and their revenues

Hayford (2007) in his formal analysis of corruption accepted the assuptions of Cournot model where the bribe taker takes the level of the per-unit bribes of the other bribe takers and chooses the per unit bribe to maximize the bribe revenue R_i. His conclusions stated that with increasing number of individuals accepting bribes there is an increase in the sum of per unit bribes which asymptotically approaches the amount that would completely terminate the relevant market. The increase in number of bribe takers means the increase in the amount of corruption itself. Intuitively there should be a negative effect on revenue received with bribe with strengthening the corrupted environment, supported by the dead weight loss of such system that increases in number of bribe takers at a diminishing rate. All in all, most important implication of the examination is that if '*bribe takers collude and split the revenue'* from bribes, both bribe takers and bribe payers '*would be better off*.' The statement is consistent with the characteristic of Cournot model as well as the conclusions of different authors dealing with corruption and its economic effects. [31]

8.3 Dead weight loss and honesty

Guel and Fischbaum (1996) based their estimation of allocative inefficiency in the pharmaceutical industry on computing the differences between the highest prices and the lowest prices of the most popular prescription drugs on the market in UK and US. Although it is not possible to implement the model for Czech case, as described in chapter 4, there are several significant conlusions we should further take into consideration. First of all, their regression showed that ,*competition did not decrease dead weight loss (DWL) per dollar sales'* as expected but in the case of generics ,*it even*

[31] Hayford (2007), Waller, Verdier, Gardner (2002), Easterly (2001), Mauro (1998)

increased it.' It stems from the specification of generics itself, as price sensitive consumers prefer cheaper generic drug immediately after its introduction to the market and consumers prefering branded original product with all its pros are willing to accept even higher prices which decreases the price elasticity of demand and therefore increases the prices of original drugs. Secondly, the regression showed ,*sales volume had not significant effect on DWL per dollar sales*.' That would reassure us even if the Czech market is relatively small compared to European market and EU market is minor compared to World market, the existing competition and regulation is comparable effective as it were in the case of much bigger markets. All in all we cannot estimate DWL empirically based on the differences of drugs' prices, however, we can try to do that theoretically and with respect to occurrence of unethical behaviour.

The question to be asked to proceed is what conclusions towards firms' incentives for regulation of unethical behavior can be extracted from the first part of the model since it shows without further assumptions it is irrational to expect reduction of corruption from the bribe takers' initiative. To be precise the maintanance of corruptible environment is economically convenient to bribe takers. However, there are plenty of reasonable arguments related specifically to pharmaceutical industry that could ensure sufficient motivation. The doctor prescribing drugs based on corruption rather than knowledge and expert opinion risks not only the reputation but also the diploma and with lower probability that is still above zero even a crime trial. Although it would be rather naïve to develop rationale for ethical behaviour that way and the conclusion would probably be easily questioned, we have already showed it is much easier to show producers' incentives for generally accepted ethical conduct. Moreover the firms decide whether to offer a bribe or not exclusively on their own. The most preferred way to reduce corruption is therefore to make an association of '*the potential bribe payers'* and make an effort to create transparent and ethical environment easily observable by the public that becomes more and more sensitive to potential bribery attempts. [32]

[32] Which correlates with the theory of corruption culture perceived empirically e.g. in post-socialist countries or analyzed specifically by distinct authors, e.g. Olson (2000)

8.4 Self-Regulatory Organizations

As prescription drugs fit the credence goods description, one of the most suitable models seems to be the one analyzed by Nunez in 2001 and in extended version in 2007. The main research question is whether SROs have the sufficient incentives to '*monitor quality and expose fraud to the public'* even if we take into consideration that quality is determined directly by the members and potential fraud could damage reputation of the SRO itself. Alternatively, the purpose is to show the assumptions for objective and effective monitoring. Another available applicable model has been an extension of classical Becker's (1968) ideas designed by Donabedian (1995) as he concentrated on the enforcement of internal professional codes. The main research questions are '*what the sources of a profession's authority over its members are'* and searching for the factors that cause '*society to rely on professional self-regulation'* rather than on other alternatives. Intuitively, quality is partly observable by consumers as well as the government organization[33]. Secondly, SRO exists in the competition of other SROs and is forced to defend its reputation as objective, independent, trustworthy institution by revealing the potential frauds and take adequate exemplary actions. Thirdly, there is tough competition between the members of SRO and in case of favoring one member, other would investigate potential corruption. As for the decisions of firms within SRO, according to Donabediad's (1995) study '*they are minimizing the expected loss from violating behavior codes.'* Furthermore, *exit costs* (Hirschman (1970)) need to be taken into consideration too, as the membership in SRO is voluntary and company can leave the organization anytime especially when preferred to submiting to punishment. Exit costs depend on an industry type and structure as well as situation across the society and the cost of leaving the group creates an upper bound to professional self-regulatory power. What can be beneficial from this approach is the crucial issue of setting efficient *'allocation of enforcement between professional authority and government authority.'*[34]

[33] On the other hand, as stated before, prescription drugs and especially activities "behind the scene" (e.g. pressures on doctors to prescribe the medicines of particular producer) cannot be properly observed and appraised by public and non-experts = credence goods

[34] two-tier regulation (discussed in 7.2 using e.g. Doyle (1997))

There is also the question to what extent can the reliability of self-regulation be explained by size of exit cost. Finally, we argue this model is probably not perfectly suitable to our case as expected loss and exit costs are strongly correlated. Also it seems to be much more likely applicable to the analysis of doctors' professional codes than firms' ethical codes.

Firstly, we have already discussed the volume of dead weight loss (chapter 8.1 and 8.3) and negative effect on reputation of the individual firm and whole industry (chapter 6) resulting from the corruption. Even though Di Tella (1997) as well as Swensson (1999) suggest a positive correlation between bribes and profits of particular firms, in the end their findings admit the more profitable firms are forced to pay higher bribes by which they simultaneously '*drive the competitors out of the market*.'

Secondly, there are transaction costs of corruption which form additional expenditures burdening a pharmaceutical firm as a potential bribe payer to the whole process. Furthermore, from the point of view of the unethical firm there exist certain hidden risks, e.g. bribe payer cannot be sure whether either a corrupted doctor will complete his part of unethical deal or the doctor understands correctly what the bribe has been paid for at all and in case of risk averse bribe payer the costs are often even higher as the model considers.

Without assessing its effectiveness, the current system of drugs' pricing cannot be overlooked here. The maximum producer's price is set by a reference system based on the cheapest substitutes in observed countries and therefore significantly limits the possibility of bribes as those would reduce maximal possible profits.

All in all there are plenty of reasons why the ethical environment where everyone is acting transparently and in compliance with generally accepted rules is preffered to a corrupted environment by both pharmaceutical companies (sellers) and patients (buyers). However, without integrated rules and their effective enforcement, there would

immediately arise an effort of any of the firms to bribe the doctors in an ethically 'pure' environment.

8.5 SRO and Public Parallel Regulation

Fortunately, there are several specific features of relevant market that enables us to set sufficient incentives for effective self-regulatory activities after forming SRO as an organization that defines, considers and enforces the unified rules.

Regulatory capture that stems from the identical incentives of the SRO as a regulator and regulated firms that form SRO is the main concern of whether SRO can operate effectively and fairly or not. Nunez (2007) examines ‚*reputation-based incentives of SRO to detect and expose consumer fraud commited by its members and the members' incentives to bribe the SRO in exchange for a cover-up to avoid external punishment*' and his formal analysis helps us to make a progress with our investigation. There are three main features of self-regulatory system according to Nunez (2001) and (2007):

1. SRO faces a *principal-agent problem* -> quality is determined by the SRO members
2. mostly *reputation-based incentives* of SRO
3. demand for existence of SRO mostly in industries supplying *credence goods*

There still remains the query if the case of ethical self-regulation within Czech pharmaceutical industry is consistent with the conclusion stating that even ‚*bribed SRO yields more vigilance and lower fraud than no self-regulation at all.*' For that purpose we define a simple framework for basic model that is justifiable thanks to meeting three main features of self-regulatory system Nunez (2007) mentioned above. According to the findings of the author only ‚*public parallel regulation*' enhances quality of SRO activities to the sufficient level.

All in all, each member maximizes the net expected value of fraud that can be expressed as the profit generated by the sales of the drugs prescripted by the bribed doctors. Moreover the producer can develop less quality drug that is less costly and it is still being prescibed to the patients. Here stemps a little inconsistency as discussed in 9.1. However, the findings of Nunez (2007) can still be used for our purpose as the slope of the member's reaction function derived from the maximization equation means the optimal value of fraud decreases with the level of SRO vigilance. Hence the task is to investigate whether SRO in Czech conditions has sufficient incentives to keep the high level of oversight and providing information to public. As the oversight is mostly done by competitors themselves the crucial incentives are again incentives of the SRO members to achieve ethical industry environment. Providing information related to unethical conduct of a competitor to the public should be a self-evident custom in the highly competitive industry. However, according to the SRO head representatives, the media has often used inaccurate generalization when informing about violations in the pharmaceutical industry over the past years. Although there is a trend of improving, negative stimulus has been created. Therefore it is inevitable to form as precise and straight parallel monitoring of drug producers as we want them to be.

Anyways if the aim is to monitor as much existing fraud as possible even the corruptible SRO is prefered to no regulation at all as it is motivated to make an effective oversight to create situations when the bribes are offered. Public parallel regulation in our case include not just state regulators but also the media that cover particular cases and also perform their own investigations and different specialized groups often called as watchdogs institutions. [35] The conclusion can be supported by Czech empirical evidence where the results of clinical and postmarketing studies have been improving over time according to leading representatives of both state regulatory body SUKL and SROs.

[35] E.g. IMS Health

8.6 Governmental delegation of regulation

As indicated before there are several incentives of SRO and its members not to expose the fraud publicly: reputation of the industry and SRO directly connected with the reputation of its members, possible law suits and therefore additional expenditures etc. Therefore importance of discussed *public parallel regulation* in our setting lays mostly in another permanent possibility of statutory regulation that motivates SROs to stay trustworthy as their existence is dependent on willingness of deregulation by rather exposing the frauds themselves - more effectively.

Therefore, approval of the government is necessary as it is entitled to take over those new rules and enforce them by its own. Last but not least government's incentives *to persist with self-regulation* (delegating) or *to introduce the statutory regulation* (legislating) should be taken into consideration using the formulations assumed by Ashby, Chuah, Hoffmann (2003).[36] For simplicity, they assumed an industry of '*two identical firms simultaneously choosing between comlying (c) and violationg (v) a self-regulation'* and the government reacting subsequently. According to them, there are following possible gains and losses for the participants (firms and government):

+		-	
A	government benefit from complete industry abatement	R	government cost of statutory regulation
a	government benefit from partial industry abatement	r	government cost of self-regulation
B	firm relative benefit from self-regulation (abatement cost under statutory regulation minus abatement under self-regulation)	C	industry administrative cost of self-regulation

Figure 24: Notion of Ashby, Chuah, Hoffmann (2003)

To sum it up, each of two identical firms within common industry decides to comply or to violate and the government subsequently chooses either delegation or regulation of the industry. Based on Figure 24 abbreviations, let us detect resulting payoffs of each participant for every possible alternative in such a model:

[36] Ashby S., Chuah S.H., Hoffmann R.: Industry Self-Regulation: A Game-Theoretic Typology of Strategic Voluntary Compliance

simultaneously		followed by	Firm A: payoff		Firm B: payoff		Government: payoff	
Firm A	**Firm B**	**Government**	**+**	**-**	**+**	**-**	**+**	**-**
comply	comply	legislating		C/2		C/2	A	R
comply	comply	delegating	B	C/2	B	C/2	A	r
comply	violate	legislating		C			A	R
comply	violate	delegating	B	C	B		a	r
violate	comply	legislating				C	A	R
violate	comply	delegating	B		B	C	a	r
violate	violate	legislating					A	R
violate	violate	delegating	B		B			r

Figure 25: Payoffs of particular market players. Based on notion by Ashby, Chuah, Hoffmann (2003)

As governmental costs of self-regulation are lower than those of statutory regulation, [37] naturally, the government would prefer delegating the regulation in case both firms comply with the requirements of self-regulation. However there is no direct positive benefit component for firms in the model and at the same time they would still have to burden costs of the voluntary self-regulation. We need to look back to the previous parts of this chapter to find relevant incentives for firms to behave in that way. Those have shown that violation of ethical rules would on one hand arouse violation of other firm to even greater extent, on the other hand both firms would shrink their profits. That is in contrary to another conclusion from this model which tells us that alternative of both firms violating the self-regulatory system and the government delegating agency to enforce self-regulation would be the most convenient outcome for firms. Implemented to our case we can assume it would be only possible scenario if there were no controlling mechanisms and consistently with the presented model it would be also the worst solution for the government and therefore not possible as the government is there to take an action, not to ignore such market failures. Additionally there are six more possibilities left, that cannot be compared (from the point of interest of the government) unless the relative sizes of A - R, a - r are known. In case A-R > a-r, the authors Ashby, Chuah, Hoffmann (2003) speak about '*zero tolerance regime'* as the government prefers the statutory regulation unless there is a total industry compliance. On the other hand, if A-R < a-r, it is called '*partial tolerance regime'* and the government accepts self-regulation

[37] Intutive conclusion of chapter 5

even if only one firm of the two complies. The further considerations are not neccessery for our model.

The greatest payoff for the government arises when both firms comply with ethical code of conduct and it allows them to enforce it on their own. Therefore incentives of government to delegate responsibility of regulation are justified for our case. The advantages and disadvantages of both statutory and self-regulatory regimes are compared in chapter 5.

8.7 Other possible extensions of the model

Most of the relationships between SRO and public in existing literature have been discussed using a Cournot model, however there is plenty of literature dealing with Stackelberg model when setting the self-regulatory framework too. Another possible extension consideres competing SROs which might not be the case of Czech republic. Although there are three SROs they are rather cooperating than competing while targeting different types of members. Also Heyes (2001) provides an idea of alternative extension based on adaptive modelling where SRO has '*the ability to target its enforcement effort according to the previous peformance of individual firms*.' Last but not least the economics and ethics as well as theory of corporate social responsibility provide their own theoretical approaches to the topic. However, the most significant possible extension based on previous findings would be a distinction between original and generic drugs in a formal analysis too.

8.8 Conclusion

All in all, original aim of showing incentives of firms' sincere self-regulation practices concerning ethical conduct has been undoubtedly achieved while assumptions of status quo, including specific features of relevant market and both actual and eventual statutory interventions have been assumed. To be able to responsibly recommend further

liberalization of rules in the industry, there would be much more measurable information needed.

9 Conclusion of the study and Future prospects

The conclusion of results obtained by the theoretical approach combined with verbal analysis is the confirmation of recommendation of ‚*two-tier regulation*'. It includes both self-regulation and public parallel regulation led by a governmental oversight and media forming public opinion. Combined form of regulation is the most likely the most beneficial alternative primarely for the consumers and secondary for all the players on the market, as SRO has ‚*informational advantage*' and PR creates ‚*the reputation-based incentives to monitor quality*' such that would probably have not existed otherwise. Statutory regulation by its own is highly ineffective as for example the support of education of the doctors through conferences, lectures cannot be instantly considered an unethical conduct. On the contrary the reasonable extent of doctors' support can be socially beneficial and the government would not be able to effectively set a burden between beneficial support and unethical behaviour, because there is detailed first-hand knowledge and experience required. To avoid creating opportunities for SRO and its members to misuse their informational advantage there is a consensus implemented on the market: parallel public regulation which has been developing by distinct activities initiated both by state and SROs as availability of information is strongly needed for trustworthy surveillance. One of the projects in preparatory phase towards the improvement of their possibilities to monitor firms' behaviour towards doctors is a list of all events for doctors sponsored by pharmaceutical companies with detailed information publicly available and regularly updated. The incentive to accept that invention by most of the companies is related to the incentives of voluntary self-regulation itself. From another point of view the objectivity of medical doctor prescribing the drugs have to be ensured too what seems to create a vicious circle solvable again only by proper enforcement of ethical standards. In these cicumstances the confirmation of hypothesis stating the self-regulation with corruption should be economically preferred to no self-regulation at all can be considered a great success. Such a statement can be grounded

partly on our verbal analyses of particular features of the examined industry and partly on findings of discussed papers and other literature.

Finally, the eventual extension of this thesis could also attempt to answer a question whether the trends in informal regulation in Czech pharmaceutical industry are going in a right direction. Although they obviously follow the patterns of more developed economies with longer and deeper tradition of informal regulation and they are consistent with orientation of development on European level, these do not assure the optimal solutions‘ orientations themselves. However, the existing efforts of attaining the most effective possible regulatory regime given all the preconditions seem to be sincere considering all the monitoring mechanisms as well as firms‘ individual and industry’s overall incentives.

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Předpokládaný název BP:

European Competition Policy and its Main Features: Focus on the Czech Pharmaceutical Market

Charakteristika tématu, současný stav poznání, případné zvláštní metody zpracování tématu:

The thesis focuses on European competition policies and the interaction of the formal and informal regulation of competition practices on the example of the Czech pharmaceutical market.

The thesis consists of two parts. The first one is philosophically descriptive, describing characteristic features, principles and objectives of current European competition policies and outlining the institutional and legal framework of such policies.

The second part is a case study of a specific application of formal and informal regulation in the Czech Republic. It concentrates on the competition practices, current legal framework and recently formulated self-regulation rules in the Czech pharmaceutical industry. The aim is to

evaluate the present situation on the relevant market and to asses the efficiency and viability of self-regulation versus governmental regulation.

Struktura BP:

European Competition Policy's Characteristics and Targets
Policy Areas of European Commission Towards European Competition Policy and International Cooperation: Basic Principles and Legislation
Liberalization in Central European Area

Analysis of Formal and Informal Regulations in Czech Pharmaceutical Industry
Self-regulation Rules on the Pharmaceutical Market and its Immediate Consequences
An Evaluation of the Current State on the Relevant Market

Seznam základních pramenů a odborné literatury:

Becker, G. S.: Public Policies, Pressure Groups, and Dead Weight Costs, in: Stigler, G. J.: Chicago Studies in Political Economy, pp. 85-105, The University of Chicago Press, Chicago and London 1988

Peltzman, S.: Toward a More General Theory of Regulation, in: Stigler, G. J.: Chicago Studies in Political Economy, pp. 234-266, The University of Chicago Press, Chicago and London 1988

Grajzl P., Murrell P.: Allocating law-making powers: self-regulation vs. government regulation

Crew, M.A., Spiegel, M.: Obtaining the best from regulation and competition, New York, NY [US] : Kluwer Academic Publishers, 2005

http://ec.europa.eu/comm/competition/international/overview/index_en.html
http://www.ncpa.org/pi/health/hedex7m.html
http://www.efpia.org/Content/Default.asp
http://www.aifp.cz/cz/index.php
http://www.mfcr.cz/cps/rde/xchg/

Interviews with Representatives of Czech Pharmaceutical Companies

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